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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,989	02/05/2004	Paul A. Iaizzo	P-8965.00	5392

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,989	IAIZZO ET AL.	
	Examiner	Art Unit	
	Eric D. Bertram	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,13-24,26-28 and 30-35* is/are rejected.

7)☒ Claim(s) *8, 12, 25 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *020504*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 02/05/2004 was filed within three (3) months of the mailing date of the application on 02/05/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

3. The abstract of the disclosure is objected to because it does not provide a complete, technical disclosure of the invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 5-7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by King (4,282,886). King discloses a medical lead, which is in this case an epicardial lead 10 (Col. 2, Line 7), comprised of a lead body with a distal end (Col. 2, Line 45) and a glue segment 16 (Col.2, Line 21), as shown in Figure 3. The glue segment is composed of a tissue adhesive designed to adhere to the exterior of the heart (Col.1, Line 51). In figure 3, King shows a guard disposed in proximity to the glue segment, which is foil 16a covering the adhesive to protect it (Col. 2, Line 25). In figure 1, King shows the glue segment to be in an annular shape, and shows in figure 3 that the glue segment is also in a tubular shape. In regards to claim 14, King describes the process of adhering the medical lead to the tissue of the heart wall using a tissue adhesive (Col. 2, Line 57).

6. Claims 1,2,6,10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Parry et al. (6,718,212). Parry discloses a medical lead, which is in this case an epicardial lead 50 (Col. 8, Line 32), comprised of a lead body with a distal end (Col. 1,

Line 10) and a glue segment (Col. 9, Line 54). The glue segment is composed of a tissue adhesive designed to adhere to the epicardium of the heart (Col.10, Line 16). As shown in figure 4, the glue segment 54 is formed in an annular shape and the lead is comprised of tip electrode 56. Furthermore, the glue segment 54 is shown to be disposed about the tip electrode 56 in figure 4.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Hammerslag (5,383,899). King discloses the applicant's basic inventive concept as described above with the exception of the use of n-butyl cyanoacrylate as the tissue adhesive. Column 5, line 14 of Hammerslag shows n-butyl cyanoacrylate to be a known tissue adhesive in the art. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Hammerslag to modify the tissue adhesive of King by using n-butyl cyanoacrylate in the glue segment in order to have an adhesive that hardens rapidly (Col. 5, line 35).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Munch et al. (6,463,335). King discloses the applicant's basic inventive concept as described above with the exception of the use of fibrin glue as the tissue adhesive. Column 19, line 2 of Munch shows fibrin-based glue to be a known tissue adhesive in the art. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Munch to modify the tissue adhesive of King by using fibrin-based glue in the glue segment in order to obtain rapid immobilization of the electrode and allow for faster surgical procedures (Col.18, line 62).

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Theeuwes et al. (6,726,920). King discloses the applicant's basic inventive concept as described above with the exception of the glue segment having dots of

tissue adhesive. Column 20, line 50 of Theeuwes discloses using several adhesive spots 32 (see figure 2D) in order to adhere a lead to an organ surface. It would have been an obvious manner of design choice to have the glue segment of King formed of "dots" or "spots," since such a modification is generally recognized as being within the level of ordinary skill in the art and offers no disclosed advantage over other arrangements.

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of Williams et al. (6,516,230). Parry discloses the applicant's basic inventive concept as described above with the exception of the tip electrode being formed of a helix-coil. Column 3, line 5 of Williams discloses a tip electrode 16 (see Figure 3a) taking the form of a helix. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Williams to modify the tip electrode of Parry by forming it into a helix in order to provide a more secure connection of the electrode to tissue.

14. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Igo et al. (6,666,844). King discloses the applicant's basic inventive method as described above with the exception of the steps of advancing the medical lead through a catheter and suctioning moisture from the attachment site. Column 9, line 31 of Igo describes a cardioregulation lead that has been advanced up the catheter to the attachment site as shown in figure 11. Column 6, line 65 of Igo discloses a passage 120 that is to supply a vacuum to withdraw fluid. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Igo to

modify the process of King by adding the steps of advancing the medical lead through a catheter and suctioning moisture from the attachment site in order to provide a method of affixing a lead to the heart without using invasive surgery (Col. 3, line 8).

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Starksen (5,571,161). King discloses the applicant's basic inventive method as described above with the exception of the steps of advancing the medical lead through a catheter and inflating a balloon at the attachment site. Column 5, line 60 of Starksen describes introducing electrical lead E through the guide catheter after the distal balloon has been inflated (Col. 5, line 53), as shown in figure 8D. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Starksen to modify the process of King by adding the steps of advancing the medical lead through a catheter and inflating a balloon near the attachment site in order to provide a method of affixing a lead to the heart without using invasive surgery.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Sigg et al. (6,931,286). King discloses the applicant's basic inventive method as described above with the exception of the step of urging tissue adhesive through a lead lumen. Column 7, line 9 describes introducing a fluid delivery device through the lumen of a lead body. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sigg to modify the process of King by adding the steps of advancing a fluid, which in this case is tissue adhesive, through a lumen in the lead in order to apply the tissue adhesive to the application site.

17. Claims 18, 19, 22-24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Starksen (5,571,161). King discloses the applicant's basic inventive concept as described above with the exception of a catheter with a balloon disposed at the distal end through which the medical lead could be advanced. Column 4, line 9 of Starksen describes a catheter with a lumen large enough in diameter to accommodate a cardiac lead. Column 4, line 34 of Starksen discloses an inflatable balloon attached at the distal end of the catheter. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Starksen to modify the system of King by adding a catheter with a balloon attached to the distal end through which the lead could be advanced to the application site in order to provide a method of affixing a lead to the heart without using invasive surgery. In regard to claim 19, King discloses a glue segment composed of a tissue adhesive designed to adhere to the exterior of the heart (Col.1, Line 51). In regard to claim 22, King shows a guard disposed in proximity to the glue segment, which is foil 16a covering the adhesive to protect it (Col. 2, Line 25). In regard to claims 23 and 24, King shows the glue segment to be in an annular shape in figure 1, and shows in figure 3 that the glue segment is also in a tubular shape.

18. Claims 18, 19, 27, 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of Starksen. Parry discloses the applicant's basic inventive concept as described above with the exception of the catheter through which the medical lead could be advanced. Column 4, line 9 of Starksen describes a catheter with a lumen large enough in diameter to accommodate a cardiac lead. It would have

been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Starksen to modify the system of King by adding a catheter through which the lead could be advanced to the application site in order to provide a method of affixing a lead to the heart without using invasive surgery. In regard to claim 27, Parry discloses a lead comprised of a tip electrode 56 as shown in figure 4. In regard to claim 30, Parry discloses a glue segment 54, shown to be disposed about the tip electrode 56 in figure 4. In regard to claim 35, Parry discloses an implantable pacemaker 58 connected to lead 50 (Col. 9, line 20) as shown in figure 3.

19. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Starksen and further in view of Hammerslag (5,383,899). King, as modified above, discloses the applicant's basic inventive concept with the exception of the use of n-butyl cyanoacrylate as the tissue adhesive. Column 5, line 14 of Hammerslag shows n-butyl cyanoacrylate to be a known tissue adhesive in the art. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Hammerslag to modify the tissue adhesive of King by using n-butyl cyanoacrylate in the glue segment in order to have an adhesive that hardens rapidly (Col. 5, line 35).

20. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Starksen and further in view of Munch et al. (6,463,335). King, as modified above, discloses the applicant's basic inventive concept with the exception of the use of fibrin glue as the tissue adhesive. Column 19, line 2 of Munch shows fibrin-based glue to be a known tissue adhesive in the art. It would have been obvious to one of ordinary

skill in the art at the time of the applicant's invention from the teaching of Munch to modify the tissue adhesive of King by using fibrin-based glue in the glue segment in order to obtain rapid immobilization of the electrode and allow for faster surgical procedures (Col.18, line 62).

21. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Starksen and further in view of Theeuwes et al. (6,726,920). King, as modified above, discloses the applicant's basic inventive concept with the exception of the glue segment having dots of tissue adhesive. Column 20, line 50 of Theeuwes discloses using several adhesive spots 32 (see figure 2D) in order to adhere a lead to an organ surface. It would have been an obvious manner of design choice to have the glue segment of King formed of "dots" or "spots," since such a modification is generally recognized as being within the level of ordinary skill in the art and offers no disclosed advantage over other arrangements

22. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of Starksen and further in view of Williams et al. (6,516,230). Parry, as modified above, discloses the applicant's basic inventive concept with the exception of the tip electrode being formed of a helix-coil. Column 3, line 5 of Williams discloses a tip electrode 16 (see Figure 3a) taking the form of a helix. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Williams to modify the tip electrode of Parry by forming it into a helix in order to provide a more secure connection of the electrode to tissue.

23. Claims 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of Starksen and further in view of Sigg et al. Parry as modified above, discloses the applicant's basic inventive concept with the exception of the lead containing a lumen and the catheter including mapping electrodes. Column 7, line 9 of Sigg describes introducing a fluid delivery device through the lumen of a lead body. Column 5, line 22 of Sigg describes the use of a mapping catheter. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sigg to modify the system of Parry by adding a lumen in the lead in order to apply the tissue adhesive to the application site and to also include mapping electrodes in order to locate a desirable application site (Col. 5, line 21).

24. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Starksen and further in view of Igo et al. King, as modified above, discloses the applicant's basic inventive concept with the exception of the catheter having a suction capacity. Column 6, line 65 of Igo discloses a passage 120 in the catheter that is to supply a vacuum to withdraw fluid. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Igo to modify the system of King by adapting the catheter to apply suction to a tissue site in order to remove excess moisture from the site.

Allowable Subject Matter

25. Claims 8, 12, 25, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cahalan et al. (4,768,523) discloses a medical lead with a glue segment comprised of tissue adhesive at a distal end.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

Eric D. Bertram
Examiner
Art Unit 3762

EDB